PATENT
Docket No.: 28069-585 DIV
(Formerly 003301-072)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Nils Ove Gustavsson *et al.*	Confirmation No.:	3614
Serial No.	:	10/627,920	Customer No. :	35437
Filed	:	July 28, 2003		
Art Unit	:	1623		
Examiner	:	Krishnan, Ganapathy		
For	:	**Pharmaceutically Acceptable Starch**		

Mail Stop AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF RICHARD E. JONES UNDER 37 C.F.R. §1.132

I, Richard E. Jones, Ph.D., declare and state that:

1. I am Senior Vice President of Research and Development at SkyePharma, Inc., San Diego, CA. I have held this position for 2½ years. I earned my Ph.D. degree in physical chemistry from Stanford University. I have had over thirty years' experience in the design and development of pharmaceutical products, particularly in the areas of formulation design and characterization, and excipient (inactive ingredient) characterization. A copy of my *Curriculum vitae* is attached hereto.

2. As Senior VP of R&D at SkyePharma, I am responsible for directing formulation design, process research and development, analytical research and development, and nonclinical development (including toxicology) activities.

3. I have reviewed and understand the above-identified patent application and the final Office Action, dated February 18, 2005, in the above-identified patent application. In

this Office Action the Examiner alleges that the starch product claimed in this application is the same as a starch product resulting from molecular weight reduction by acid hydrolysis, as claimed in co-pending patent application U.S. Serial No. 10/461,393, filed on June 16, 2003, the entire right, title and interest of which is also owned by Jagotec AG.

4. I have reviewed and understand the contents of the instant patent application U.S. Serial No. 10/627,920, filed on July 28, 2003, and of patent application U.S. Serial No. 10/461,393, filed on June 16, 2003.

5. I understand that the subject matter of the independent claims in this application is generally drawn to a pharmaceutically acceptable starch which has the following characteristics:

(i) an amylopectin content in excess of 85 percent by weight, in which the molecular weight of said amylopectin has been reduced by shearing such that at least 80 percent by weight of the starch lies within the range of 10–10,000 kDa;

(ii) a purity of at most 50 μg amino acid nitrogen per gram dry weight of starch; and

(iii) can be dissolved in a concentration exceeding 25 percent by weight in water, or

(iv) lacks hydroxyethylation.

6. Based on my knowledge and experience in the area of starch production and use, and more particularly, pharmaceutically acceptable starch production and use, it is my opinion that a starch product having its molecular weight reduced by shearing as described in the instant application is distinct from a starch product having its molecular weight reduced by acid hydrolysis.

7. Based on my knowledge and experience in the field, it is my opinion that the molecular weight reduction of starch by shearing gives rise to a different molecular weight distribution of starch fragments compared with the molecular weight distribution of starch fragments produced by acid hydrolysis. Subjecting starch to

shearing to reduce the molecular weight of amylopectin results in a more narrow molecular weight distribution of the resulting starch fragments compared with acid hydrolysis. Although the acid hydrolysis process is more readily adapted to economic large-scale use (due to its advantageous purification and precipitation performance in producing microparticles), the shearing process produces a technically more elegant starch product with respect to molecular weight distribution.

8. Based on my knowledge and experience in the field, it is my opinion that starch comprising amylopectin that is subjected to molecular weight reduction by shearing is technically and discernibly different from starch comprising amylopectin that has been subjected to molecular weight reduction by acid hydrolysis.

9. The specification of the above-identified patent application also teaches that there are differences between starch prepared by shearing and starch prepared using other methods. For example, on page 18, lines 27-33, the specification discloses that via the shearing process, it is possible to obtain the desired molecular weight distribution for the resulting starch without a large proportion of unwanted low molecular weight material being formed. In addition, the specification teaches that a significantly narrower molecular weight distribution of the starch can be achieved using shearing to reduce the molecular weight of amylopectin compared with other methods.

10. Based on my knowledge and experience, and in view of the disclosure and teaching of this application, it is my opinion that a starch having the characteristic of molecular reduction by shearing is distinct and dissimilar from a starch having the characteristic of molecular weight reduction by acid hydrolysis. Thus, the two types of starch products are not the same and do not overlap.

11. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001

and that willful false statements may jeopardize the validity of this patent application and any patent issuing thereon.

Dated: 27 April 2005

Signed: _____
Richard E. Jones, Ph.D.